

REMARKS

Claims 1-6, 11-14, 17, and 19-32 are pending in the present application. Reconsideration of the application is respectfully requested in view of the following responsive remarks.

In the office action of March 3, 2006, the following actions were taken:

(1) Claims 1-6, 11-14, 17 and 19-28 were rejected under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,658,583 to Zhang et al. (hereinafter “the ‘Zhang et al.’”

(2) Claims 1, 11-14, 17, 19, 22, 23, and 27-32 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,383,848 to Hillman et al. (hereinafter “Hillman et al.” in view of U.S. Patent No. 5,427,585 to Bettinger (hereinafter “Bettinger”).

(3) Claims 14, 19, and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al.

It is respectfully submitted that the presently pending claims be examined and allowed. Applicants submit that each and every amendment herein, and throughout the prosecution of the present application is fully supported by the specification as originally filed, and that no new matter has been added.

The Present Invention

The present invention teaches methods and systems for providing controlled delivery of an analgesic through a patient's skin. The invention includes delivering an analgesic through the skin of a patient using a dermal drug delivery system. Further, the invention requires applying a temperature modification apparatus proximate the delivery site, the temperature control apparatus capable of providing on demand delivery at a predetermined temperature for a predetermined period of time. It is important to note that the term “dermal drug delivery system,” as used in claims 1, 22, and 29 has been defined in the original specification as referring to “systems in which the main driving force for drug permeation is the drug concentration gradient,” unless otherwise specified. Heat can be applied to the dermal drug delivery system, but still, the main driving force of the dermal drug delivery system *per se* is the drug concentration gradient. The presently pending claims do not specify that the term

dermal drug delivery system refers to anything other than a drug concentration gradient driven system and, as such, they clearly are intended to include only those systems.

Rejections based on the Zhang et al. reference

The Examiner rejected claims 1-6, 11, 12, 14, 19, 20-27 and 28-32 either under 35 U.S.C. § 102(b) as being anticipated by Zhang et al or under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. The Applicants have enclosed a copy of a petition filed with the Petitions Office on May 31, 2006 in which the Applicant's have corrected the priority claim of the presently pending application so that it includes the relationship or status of the present application with respect to the previously presented priority chain. In particular, the petition makes clear that the present application is a continuation-in-part of U.S. Patent Application Serial Number 09/878,558 which in turn traces its priority back to the cited reference, namely U.S. Patent No. 5,658,583. The Applicants submit that the entire delay for filing the proper claim of benefit was unintentional.

It is noted that the proper inclusion of the benefit claim, as set forth in the enclosed petition, creates a priority chain back to U.S. Patent No. 5,658,583 (Zhang et al.) which in turn renders the present rejections based on Zhang et al. moot. In light of the petition, Applicant's respectfully request that the Examiner stay further action on the present application until a decision is made by the Petitions Office regarding the benefit claim.

Rejections based on Hillman et al. in view of Bettinger

Claims 1, 11-14, 17, 19, 22, 23, and 27-32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. in view of Bettinger. Hillman et al. teaches methods, formulations, and systems for improved iontophoretic administration of drugs. In one embodiment, a pretreatment is used in which a "hot pack is applied to the skin 10 minutes prior to drug delivery...." Col. 25, ll. 61-67. The delivery of the drug was done iontophoretically after the pretreatment of the skin using the "hot pack." Col. 25, l 69 to Col. 26, l. 1. As noted by the Examiner in the Office Action, Hillman et al. does not teach a temperature modification apparatus or the claimed temperature. In addition, Hillman et al. fails to teach the use of a dermal

drug delivery system as required by the each of the presently pending independent claims, i.e. where a concentration is gradient is used as the main driving force of the drug. Instead, the drug delivery taught in Hillman et al. is iontophoretic delivery, which utilizes electricity as the driving force to deliver the drug. The “dermal drug delivery system” as claimed in all of the independent claims does not read on iontophoretic delivery.

Bettinger also teaches an iontophoretic medication patch having a heating element for pre-treating the skin prior to iontophoretic drug delivery. Col. 3, ll. 8-14, *see also* Claim 1, col. 4, ll. 45-57. Like Hillman et al., Bettinger also fails to teach the use of a dermal drug delivery system, i.e. where a concentration is gradient is used as the main driving force of the drug. The driving force for delivery in the Bettinger disclosure is iontophoretic or electricity.

As discussed above, the present invention requires the use of a dermal drug delivery system. The specification clearly states that, unless otherwise specified, the term dermal drug delivery system is limited to “systems in which the main driving force for drug permeation is the drug concentration gradient.” As no other definition of the term is specified in the claims, the term is limited to those systems in which the driving force for drug permeation is the drug concentration gradient. Both Hillman et al. and Bettinger use iontophoretic means as the “primary driving force” for drug permeation, and do not teach the use of heat in combination with systems in which the primary driving force is the drug concentration gradient.

In addition, neither Hillman et al. nor Bettinger teach the requirement that the heat be applied at a predetermined temperature for a predetermined period of time. The use of heat with transdermal administration of analgesic drugs is potentially dangerous as the heat increases the delivery of the drug, which left uncontrolled could cause serious consequences, including overdose or death. *See* Example 2 on page 30 of the original specification. Similar to the duration of the treatment, the temperature of the heating can impact the rate of drug permeation as well as the comfort of the patient, and in some cases, the stability of the drug. Therefore, having a predetermined temperature range and a predetermined period of administration aids in preventing undesirable side effects while facilitating the absorption of the drug. As neither Hillman et al. nor Bettinger teach the use of heat with a dermal drug delivery device (as defined in the specification) or applying the heat at a predetermined

temperature for a predetermined period of time, each and every element of the independent claims is not taught. As such, the cited references do not render the presently pending claims obvious and it is respectfully requested that this objection be withdrawn.

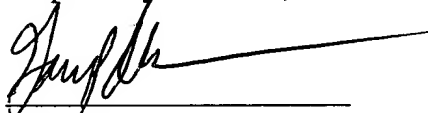
CONCLUSION

In view of the foregoing, Applicants believe that claims 1-6, 11-14, 17, and 19-32 present allowable subject matter, and allowance is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 5th day of June, 2006.

Respectfully submitted,



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Of:

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COPY

Patent Application No. 09/954,904

Attorney Docket No. 24055.CIP2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Jie Zhang	CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8
SERIAL NO.:	09/954,904	I hereby certify under 37 CFR § 1.8 that this correspondence is being facsimile transmitted to the USPTO or being deposited with the United States Postal Service with sufficient postage as first class postage in an envelope addressed to Commissioner of Patents Alexandria, VA 22313 on the date indicated below.
FILED:	9/18/2001	<u>Brenda Wiseman</u> Brenda Wiseman
FOR:	METHODS AND APPARATUS FOR IMPROVED ADMINISTRATION OF ANALGESICS	<u>6/5/06</u> Date of Deposit
ART UNIT:	1616	
EXAMINER:	George, Konata M	
DOCKET NO.:	24055.CIP2	

SUBMISSION OF A PETITION TO ACCEPT AN UNINTENTIONALLY DELAYED CLAIM FOR THE BENEFIT OF A PRIOR-FILED APPLICATION UNDER 37 C.F.R. § 1.78(a)(3)

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a submission of a petition to correct a claim for the benefit of a prior-filed patent application pursuant to 37 C.F.R. 1.78(a)(3). The appropriate fee in accordance with 37 C.F.R. 1.17(t) is submitted herewith.

COPY

Patent Application No. 09/954,904
Attorney Docket No. 24055.CIP2

REMARKS

Applicants submit this petition to amend a claim for the benefit of a prior-filed patent application pursuant to 37 C.F.R. 1.78(a)(3). Applicants submit that the entire delay for filing the proper claim of benefit was unintentional and respectfully requests acceptance of this petition.

COPY

Patent Application No. 09/954,904
Attorney Docket No. 24055.CIP2

PARAGRAPH REQUIRED BY 35 U.S.C. 120 AND 37 C.F.R. 1.78(A)(2)

Please replace the paragraph entitled "Related Applications;" which begins on page 2, line 5 of the original application, with the following paragraph which meets the requirements set forth in 35 U.S.C. 120 and 37 C.F.R. 1.78(a)(2).

COPY

Patent Application No. 09/954,904
Attorney Docket No. 24055.CIP2

“Related Applications: The present application is a continuation-in-part of United States patent application serial number 09/878,558 filed June 11, 2001, issued as U.S. Patent No. 6,756,053; which is a continuation-in-part application of United States patent application serial number 09/162,587, filed September 29, 1998 issued as U.S. Patent No. 6,284,266; and which is also a continuation-in-part of United States Patent application serial number 09/545,496 filed April 7, 2000, issued as Patent No. 6,465,006; which is a divisional application of United States patent application serial number 09/162,890 filed September 29, 1998, issued as U.S. Patent No. 6,245,347; which is a continuation-in-part of United States patent application serial number 08/819,880 filed March 18, 1997, issued as U.S. Patent No. 5,919,479; which is a divisional of United States patent application serial number 08/508,463 filed July 28, 1995, issued as U.S. Patent No. 5,658,583.”

Patent Application No. 09/954,904
Attorney Docket No. 24055.CIP2

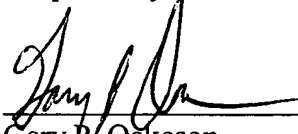
COPY

CONCLUSION

The required fee is enclosed herewith.

Dated this 5th day of May 2006.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gary P. Oakeson", is written over a horizontal line.

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PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	09/954,904
	Filing Date	9/18/2001
	First Named Inventor	Jie Zhang
	Art Unit	1616
	Examiner Name	George, Konata M.
Total Number of Pages in This Submission	Attorney Docket Number	24055.CIP2

ENCLOSURES (Check all that apply)		
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<div>Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Thorpe North & Western, LLP		
Signature			
Printed name	Gary P. Oakeson		
Date	6/5/06	Reg. No.	44,266

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature			
Typed or printed name	Katherine C. Johnson	Date	6/5/06

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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